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NOTICE OF ALLOWANCE AND FEE(S) DUE

7590 09/20/2004

FOLEY & LARDNER
3000 K STREET NW
SUITE 500
PO BOX 25696
WASHINGTON, DC 200078696

EXAMINER
CROUCH, DEBORAH

ART UNIT	PAPER NUMBER
1632	16

DATE MAILED: 09/20/2004

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/443,184	05/17/1995	WILLIAM H. VELANDER	30523/125	3827

TITLE OF INVENTION: TRANSGENIC NON-HUMAN MAMMALS PRODUCING FIBRINOGEN INTHEIR MILK

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$665	$0	$665	12/20/2004

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PTOL-85 (Rev. 09/04) Approved for use through 04/30/2007.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

7590 09/20/2004

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Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (703) 746-4000, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

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APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$665	$0	$665	12/20/2004

EXAMINER	ART UNIT	CLASS-SUBCLASS
CROUCH, DEBORAH	1632	800-007000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are enclosed:
- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s):
- ☐ A check in the amount of the fee(s) is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Director is hereby authorized by charge the required fee(s), or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.
- ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

The Director of the USPTO is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above.
NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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Determination of Patent Term Extension or Adjustment under 35 U.S.C. 154 (b)
(application filed prior to June 8, 1995)

This patent application was filed prior to June 8, 1995, thus no Patent Term Extension or Adjustment applies.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (703) 305-1383. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

PTOL-85 (Rev. 09/04) Approved for use through 04/30/2007.

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Notice of Fee Increase on October 1, 2004

If a reply to a "Notice of Allowance and Fee(s) Due" is filed in the Office on or after October 1, 2004, then the amount due will be higher than that set forth in the "Notice of Allowance and Fee(s) Due" because some fees will increase effective October 1, 2004. See Revision of Patent Fees for Fiscal Year 2005; Final Rule, 69 Fed. Reg. 52604, 52606 (May 10, 2004).

The current fee schedule is accessible from WEB site (http://www.uspto.gov/main/howtofees.htm).

If the fee paid is the amount shown on the "Notice of Allowance and Fee(s) Due" but not the correct amount in view of the fee increase, a "Notice of Pay Balance of Issue Fee" will be mailed to applicant. In order to avoid processing delays associated with mailing of a "Notice of Pay Balance of Issue Fee," if the response to the Notice of Allowance is to be filed on or after October 1, 2004 (or mailed with a certificate of mailing on or after October 1, 2004), the issue fee paid should be the fee that is required at the time the fee is paid. See Manual of Patent Examining Procedure (MPEP), Section 1306 (Eighth Edition, Rev. 2, May 2004). If the issue fee was previously paid, and the response to the "Notice of Allowance and Fee(s) Due" includes a request to apply a previously-paid issue fee to the issue fee now due, then the difference between the issue fee amount at the time the response is filed and the previously-paid issue fee should be paid. See MPEP Section 1308.01.

Effective October 1, 2004, 37 CFR 1.18 is amended by revising paragraphs (a) through (c) to read as set forth below.

Section 1.18 Patent post allowance (including issue) fees.

(a) Issue fee for issuing each original or reissue patent, except a design or plant patent:
- By a small entity (Sec. 1.27(a)) $685.00
- By other than a small entity $1,370.00

(b) Issue fee for issuing a design patent:
- By a small entity (Sec. 1.27(a)) $245.00
- By other than a small entity $490.00

(c) Issue fee for issuing a plant patent:
- By a small entity (Sec. 1.27(a)) $330.00
- By other than a small entity $660.00

Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

PTOL-85 (Rev. 09/04) Approved for use through 04/30/2007.

Notice of Allowability	Application No.	Applicant(s)	
	08/443,184	VELANDER ET AL.	
	Examiner	Art Unit	
	Deborah Crouch, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to *paper no. 17*.

2. ☒ The allowed claim(s) is/are *96-133*.

3. ☐ The drawings filed on _____ are accepted by the Examiner.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☒ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☒ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☒ to Paper No./Mail Date *5, 4/11/97*.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☐ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ms. Jayme Huleatt on August 10, 2004.

1. Please cancel claims 74-95.

2. Please insert the following claims:

1 --~~96~~. A method for producing biologically active fibrinogen comprising:

providing a transgenic non-human mammal whose genome comprises a first DNA segment encoding a first DNA encoding a heterologous fibrinogen Aα chain, a second DNA segment encoding a second DNA encoding a heterologous fibrinogen Bβ chain, and a third DNA segment encoding a third DNA encoding a heterologous fibrinogen γ chain, wherein each chain is derived from the same species, and wherein each of said first, second and third segments is operably linked to a cis-acting, expression promoter-containing regulatory sequence required for its expression in a mammary gland of a female transgenic non-human mammal;

allowing the expression of said first, second and third DNA segments and the production of milk containing biologically active fibrinogen in said female mammal;

collecting milk from said female mammal; and

recovering the biologically active fibrinogen from the milk.

2 ~~97~~. The method according to claim 1 ~~96~~, wherein said transgenic non-human mammal is selected from the group consisting of a rodent, rabbit, sheep, pig, goat and cattle.

3 ~~98~~. The method according to claim 2 ~~97~~, wherein said transgenic non-human mammal is a sheep.

4 ~~99~~. The method according to claim 1 ~~96~~, wherein said transgenic non-human mammal is a cow.

5 ~~100~~. The method according to claim ~~96~~ 1, wherein said promoter to which each of said first, second and third DNA segments is operably linked is selected from the group consisting of casein, β-lactoglobulin, α-lactalbumin and whey acidic protein gene promoters.

6 ~~101~~. The method according to claim ~~100~~ 5, wherein said promoter is a β-lactoglobulin promoter.

7 ~~102~~. The method according to claim ~~100~~ 5, wherein said promoter is a casein promoter.

8 ~~103~~. The method according to claim ~~100~~ 5, wherein said promoter is a whey acidic protein gene promoter.

9 ~~104~~. The method according to claim ~~96~~ 1, wherein said fibrinogen is human fibrinogen.

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10 ~~105~~. The method according to claim ~~96~~ 1, wherein said first, second, and third DNA segments comprises an intron.

11 ~~106~~. A method for producing biologically active fibrinogen comprising:

providing a first DNA segment encoding a heterologous fibrinogen Aα chain, a second DNA segment encoding a heterologous fibrinogen Bβ chain; and a third DNA segment encoding a heterologous fibrinogen γ chain, wherein each chain is from the same species, and wherein each of said first, second and third segments is operably linked to a promoter-containing regulatory sequence required for its expression in the mammary gland of a female transgenic non-human mammal;

introducing said DNA segments into a fertilized egg of a non-human mammalian species heterologous to the species of origin of said fibrinogen chains;

inserting said egg into an oviduct or uterus of a female of said mammalian species to obtain a transgenic non-human mammal whose genome comprises said DNA segments;

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breeding said mammal to produce female progeny that express said first, second and third DNA segments and produce milk containing biologically active fibrinogen encoded by said segments;

collecting milk from said female progeny; and

recovering the biologically active fibrinogen from the milk.

12 ~~107~~. The method according to claim 11 ~~106~~, wherein said transgenic non-human mammal is selected from the group consisting of a rodent, rabbit, sheep, pig, goat and cattle.

13 ~~108~~. The method according to claim 11 ~~106~~, wherein said species into which said DNA segments is introduced is a sheep.

14 ~~109~~. The method according to claim 11 ~~106~~, wherein said species into which said DNA segments is introduced is a cow.

15 ~~110~~. The method according to claim 11 ~~106~~, wherein said non-human mammal is a cow.

16 ~~111~~. The method according to claim 11 ~~106~~, wherein said first, second, and third DNA segments comprises an intron.

17 ~~112~~. The method according to claim 11 ~~106~~, wherein each of said first, second and third DNA segments is operably linked to a transcription promoter selected from the group consisting of casein, β-lactoglobulin, α-lactalbumin and whey acidic protein gene promoters.

18 ~~113~~. A method according to claim 11 ~~106~~, wherein said first, second and third DNA segments are expressed under the control of a β-lactoglobulin promoter.

19 ~~114~~. The method according to claim 11 ~~106~~, wherein said first, second and third DNA segments are expressed under the control of a casein promoter.

20 ~~115~~. The method according to claim ~~106~~ 11, wherein said first, second and third DNA segments are expressed under the control of a whey acidic protein gene promoter.

21 ~~116~~. The method according to claim ~~106~~ 11, wherein said introducing step comprises injecting said first, second and third DNA segments into a pronucleus of said fertilized egg.

22 ~~117~~. The method according to claim ~~106~~ 11, wherein said fibrinogen is human fibrinogen.

23 ~~118~~. The method according to claim ~~106~~ 11, wherein said introducing step comprises injecting said first, second and third DNA segments into a pronucleus of a fertilized egg and inserting said egg into an oviduct of a pseudopregnant female to produce a female transgenic non-human mammal whose genome comprises said DNA segments, wherein said egg and said pseudopregnant female are of the same species.

D) 24 ~~119~~. The method of claim ~~118~~ 23, wherein said female mammal is a sheep.

25 ~~120~~. The method of claim ~~118~~ 23, wherein said female mammal is a cow.

26 ~~121~~. A transgenic non-human mammal, wherein the genome of said mammal comprises:

a first DNA segment encoding a heterologous fibrinogen Aα chain,

a second DNA segment encoding a heterologous fibrinogen Bβ chain,

a third DNA segment encoding a heterologous fibrinogen γ chain, and

further wherein each chain is derived from the same species and is operably linked to a promoter-containing regulatory sequence required for its expression in the mammary gland of a host female mammal, wherein expression of said DNA segments results in the production of recoverable quantities of biologically active fibrinogen from milk of a female of said non-human mammal.

27 ~~122~~. The non-human transgenic mammal according to claim ~~121~~ 26, wherein said non-human mammal is selected from the group consisting of a rodent, rabbit, sheep, pig, goat and cattle.

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28 ~~123.~~ The non-human transgenic mammal according to claim ~~122~~ 27, wherein said non-human mammal is a sheep.

29 ~~124.~~ The non-human transgenic mammal according to claim ~~121~~ 26, wherein said non-human mammal is a cow.

30 ~~125.~~ The non-human transgenic mammal according to claim ~~121~~ 26, wherein each of said first, second and third DNA segments is operably linked to a transcription promoter selected from the group consisting of casein, β-lactoglobulin, α-lactalbumin and whey acidic protein gene promoters.

31 ~~126.~~ The non-human transgenic mammal according to claim ~~121~~ 26, wherein said first, second and third DNA segments are expressed under the control of a β-lactoglobulin promoter.

32 ~~127.~~ The non-human transgenic mammal according to claim ~~121~~ 26, wherein said first, second and third DNA segments are expressed under the control of a casein promoter.

33 ~~128.~~ The non-human transgenic mammal according to claim ~~121~~ 26, wherein said first, second and third DNA segments are expressed under the control of a whey acidic protein gene promoter.

34 ~~129.~~ The non-human mammal produced according to claim ~~121~~ 26, wherein said mammal is female.

35 ~~130.~~ The non-human mammal produced according to claim ~~121~~ 26, wherein said mammal is male.

36 ~~131.~~ A process for producing a transgenic non-human mammal comprising:

providing a first DNA segment encoding a first DNA encoding a heterologous fibrinogen Aα chain, a second DNA segment encoding a second DNA encoding a heterologous fibrinogen Bβ chain, and a third DNA segment encoding a third DNA

encoding a heterologous fibrinogen γ chain, wherein each chain is derived from the same species, and wherein each of said first, second and third segments is operably linked to a promoter-containing regulatory sequence required for its expression in a mammary gland of a host female mammal;

introducing said DNA segments into a fertilized egg of a non-human species heterologous to the species of origin of said fibrinogen chains;

inserting said fertilized egg into an oviduct or uterus of a female of said mammalian species; and

allowing said fertilized egg to develop thereby producing a transgenic non-human mammal whose genome comprises said first, second and third DNA segments, wherein female progeny of said mammal express said DNA segments in a mammary gland to produce biologically active fibrinogen in recoverable quantities in the milk of said female progeny.

~~132~~. The process according to claim ~~131~~, wherein said mammal is female.

~~133~~. The process according to claim ~~131~~, wherein said mammal is male. –

3. The title has been changed to –Transgenic non-human mammals producing fibrinogen in their milk--.

The following is an examiner's statement of reasons for allowance: Reasons for allowance:

Claims 96-133 are free of the prior art because at the time of filing, the art did not teach nor suggest transgenic non-human mammals whose genome comprised a first DNA segment encoding a heterologous fibrinogen Aα chain, a second DNA segment encoding a heterologous fibrinogen Bβ chain; and a third DNA segment encoding a heterologous fibrinogen γ chain, wherein each chain is from the same species, and wherein each of said first, second and third segments is operably linked to additional DNA segments required for expression in the mammary gland to produce recoverable quantities of biologically active fibrinogen, methods of producing such mammals or methods of producing biologically active fibrinogen in the milk of said mammals. The claims are nonobvious because transgenic mammal production is unpredictable in expressing DNA sequences sufficiently to produce fibrinogen peptides in the correct quantities to cause formation of biologically active fibrinogen within a mammary gland cell. Further, the claims are fully enabled as the specific examples in the claims demonstrated that transgenic mice produced according to the present disclosure made recoverable quantities of biologically active human fibrinogen in their milk (specification, page 27, Table 2, to page 29 and page 45-47).

Claims 96-133 are distinct from the count in interference 104,242. Naturally occurring fibrinogen does not contain a leader peptide to direct its passage through the endoplasm reticulum (Danishefsky et al (1990), page 207, col. 2, parag. 1, lines 1-5). Fibrinogen assembles in the endoplasmic reticulum into a functional symmetrical dimmer of three polypeptides (Roy et al (1991), page 4762, col. 1, parag. 5, lines 3-7). Thus, claims 74-95, which do not require a signal sequence or leader peptide associated with the fibrinogen peptides, are distinguished from the count.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 571-272-0727. The examiner can normally be reached on M-Th, 8:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0408. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Deborah Crouch

Deborah Crouch, Ph.D.
Primary Examiner
Art Unit 1632

August 19, 2004

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